K122170

510K **Summary of Safety and Effectiveness**
Intramedullary Nail Systems Instruments
Smith & Nephew, Inc.

Contact Person and Address
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Date of Summary: July 19, 2012

OCT 19 2012

Name of Device: Intramedullary Nail Systems Instruments
Common Name: Orthopaedic Surgical Instrumentation
Device Classification Name and Reference:
21 CFR 888.3020 – Intramedullary fixation rod
21 CFR 888.3030 – Single/multiple component metallic bone fixation appliances and accessories
Device Class: Class II
Panel Code: Orthopaedics/87
Predicate Devices:
Ender Nail (K811002);
TriMax Nail System (K964163);
Friedl Gliding Nail modified (K974409);
Titanium Nail System (K981529);
Friedl Gliding Nails addition smaller nails (K020240);
IP-XS Compression Nail System (K032548);
TriGen Straight Humeral Nail System (K032722);
Friedl Gliding Nails Gliding nails with chamfered blade (K033763)
TriGen InterTAN Nail (K040212)
TriGen 130° TAN Nails (K040462);
Intramedullary Hip Screw (K040656);
TriGen Adolescent TAN (K040929)
TriGen Hindfoot Fusion Nail (HFN) (K043052);
Titanium Knee Fusion Nail (K050938);
TriGen Meta-Nail Retrograde Femoral and Tibial Nails (K061019);
TriGen Stainless Steel Knee Fusion Nails (K061783);
SURESHOT TAN Nails and Accessories (K092748);
4.5mm and 5.0mm TriGen Low Profile Bone Screw (K111025);

Device Description

Subject of this Traditional 510(k) Premarket Notification are the Smith & Nephew, Inc. Intramedullary (IM) Nail Systems Instruments. The subject devices are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew IM Nails and their cleared Indications for Use. Smith & Nephew IM Nail Systems Instruments can be organized into instrument families which are categorized as follows: Torque/Tightening, trials, drills, extractors, impactors, replacements, alignment, other guides and gauges, and bone preparation.

Intended Use/Indications for Use

Smith & Nephew IM Nail Systems Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew IM Nail Systems and their cleared Indications for Use.

Trigen Adolescent TAN Nail System and Trigen 130° TAN Nail System

Smith & Nephew Trigen Adolescent TAN Nail System and Trigen 130° TAN Nail System Instruments are accessory devices and are intended to be used to assist in the implantation of the Smith & Nephew Trigen Adolescent TAN Nail System and the Smith & Nephew Trigen 130° TAN Nail System and their cleared indications for use.

Indications for interlocking intramedullary nails include:

- Simple long bone fractures
- Severely comminuted, spiral, large oblique and segmental fractures
- Nonunions and malunions
- Poly trauma and multiple fractures
- Prophylactic nailing of impending pathologic fractures
- Reconstruction following tumor resection and grafting
- Supracondylar fractures
- Bone lengthening and shortening
- Fractures that occur in and between the proximal and distal third of the long bones being treated

In addition to the indications for interlocking intramedullary nails, devices that contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability are indicated for the following:

- Subtrochanteric fractures with lesser trochanteric involvement
- Ipsilateral femoral shaft/neck fractures
- Intertrochanteric fractures

Trigen Humeral Nail System

Smith & Nephew Trigen Nail System Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Trigen System and its cleared indications for use.

TRIGEN° Humeral Nail System is indicated for:

- Proximal and/or diaphyseal fractures of the humerus
- Nonunions
- Malalignments
- Pathological humeral fractures

- Impending pathological fractures

Trigen InterTAN Nail System

Smith & Nephew Trigen InterTAN Nail System Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Trigen InterTAN Nail System and its cleared indications for use.

TRIGEN InterTAN Nails are indicated for:

- Simple long bone fractures
- Severely comminuted spiral, long oblique, and segmental shaft
- Nonunions and malunions
- Poly trauma and multiple fractures
- Prophylactic nailing of impending pathologic fractures
- Reconstruction, following tumor resection and grafting
- Bone lengthening and shortening
- Subtrochanteric fractures
- Ipsilateral femoral shaft/neck fractures
- Intertrochanteric fractures
- Intracapsular fractures

Intramedullary Nail Systems (Short Knee Nail, REVISION° Nail and Hindfoot Fusion Nail (HFN))

Smith & Nephew Intramedullary Nail Systems Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Intramedullary Nail Systems and their cleared indications for use.

The Short Knee Nail, REVISION° Nail and Hindfoot Fusion Nail (HFN) are indicated for:

- Degeneration, deformity, or trauma of both the tibiotalar and talocalcaneal articulations of the hindfoot
- Tibiocalcaneal arthrodesis
- Combined arthrodesis of the ankle and sub-talar joints
- Avascular necrosis of the ankle and sub-talar joints
- Failed total ankle replacement with sub-talar intrusion
- Failed ankle arthrodesis with insufficient talar body
- Rheumatoid arthritis
- Severe deformity secondary to untreated talipes equinovarus or neuromuscular disease
- Severe pilon fractures with trauma to the subtalar joint

SURESHOT TAN Nail Systems

Smith & Nephew SURESHOT TAN Nail Systems Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew SURESHOT TAN Nail Systems and their cleared indications for use.

SURESHOT TAN Nails are indicated for:

- Fractures of the femur including:
  - simple long bone fractures
  - severely comminuted, spiral, large oblique and segmental fractures
- Non unions and malunions
- Poly trauma and multiple fractures
- Prophylactic nailing of impending pathologic fractures
- Reconstruction, following tumor resection and grafting
- Supracondylar fractures
- Bone lengthening and shortening
- Fixation of fractures that occur in and between the *proximal third* and *distal fourth* of the femur

In addition, SURESHOT TAN Nails contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability and are indicated for the following:

- Subtrochanteric fractures;
- Intertrochanteric fractures;
- Ipsilateral femoral shaft/neck fractures;
- Intracapsular fractures.

Intramedullary Hip Screw Systems

Smith & Nephew Intramedullary Hip Screw System Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Intramedullary Hip Screw Systems and their cleared indications for use.

Intramedullary Hip Screws are indicated for:

- Intracapsular fractures of the femoral neck;
- Trochanteric or subtrochanteric fractures;
- Osteotomies for patients with diseases or deformities of the hip;
- Hip arthrodesis;
- Supracondylar fractures and distal femoral fractures using a supracondylar plate;
- Ipsilateral femoral shaft/neck fractures;
- Intertrochanteric fractures;
- Femoral neck fractures;
- Subcapital fractures;
- Comminuted neck and shaft fractures;

- Femur reconstruction following tumor resection;
- Leg length discrepancies secondary to femoral inequality;
- Prophylactic nailing of impending pathologic fractures.

Ender Nail Systems

Smith & Nephew Ender Nail System Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Ender Nail Systems and their cleared indications for use.

ENDER Nails are indicated for:

- Fracture of the neck, trochanteric, and subtrochanteric region of the femur;
- Distal femoral fractures with a distal fragment 10cm or longer
- Tibial shaft fractures
- Proximal humeral fractures

TriMax Nail System

Smith & Nephew TriMax Nail System Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew TriMax Nail Systems and their cleared indications for use.

Femoral/Recon antegrade nails and retrograde nails are indicated for:

- Shaft fractures including severely comminuted, spiral, large oblique and segmental fractures
- Non-unions and malunions
- Bone lengthening/shortening
- Severely comminuted shaft fractures
- Pathologic fractures, pseudoarthrosis, failed osteosynthesis
- Closed supracondylar fractures
- Prophylactic nailing of impeding pathologic fractures

Additonal indications for the femoral/recon antegrade include:

- Subtrochanteric fractures with lesser trochanteric involvement
- Ipsilateral femoral shaft/neck fractures

Additonal indications for retrograde nails include:

- Severly comminuted supracondylar fractures with or without difficult intra-articular extension
- Fractures that require opening the knee joint to stabilize the femoral condylar segmarnt
- Fractures above total knee implants

The TriMax Nail System is intended to be removed upon fracture healing.

TriGen Meta-Nail Retrograde Femoral & Tibial Nails

Indications for interlocking intramedullary nails include:

- Simple long bone fractures
- Severely comminuted, spiral, large oblique and segmental fractures
- Nonunions and malunions
- Poly trauma and multiple fractures
- Prophylactic nailing of impending pathologic fractures
- Reconstruction following tumor resection and grafting
- Supracondylar fractures
- Bone lengthening and shortening
- Fractures that occur in and between the proximal and distal third of the long bones being treated

In addition to the indications for interlocking intramedullary nails, devices that contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability (e.g. Femoral Antegrade Nail, Trochanteric Antegrade Nail and Femoral/Recon Antegrade Nail) are indicated for the following:

- Subtrochanteric fractures
- Intertrochanteric fractures
- Ipsilateral femoral shaft/neck fractures

In addition to the indications for interlocking intramedullary nails, devices that use a retrograde femoral surgical approach (e.g. Knee Nail, Retrograde and Supracondylar Nails) are indicated for:

- Comminuted supracondylar fractures with or without intra-articular extension
- Fractures that require opening the knee joint to stabilize the femoral condylar segment
- Fractures above total knee implants (peri-prosthetic fractures)

Knee Fusion Nails

Smith & Nephew Knee Fusion Nail Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Knee Fusion Nails and their cleared indications for use.

Knee Fusion Nails are indicated for:

- Intramedullary Knee Arthrodesis

IP-XS Compression Nail System

Smith & Nephew IP-XS Compression Nail System Instruments are accessory devices and are intended to be used to assist in the implantation of the Smith & Nephew IP-XS Compression Nail System and its cleared indications for use.

The IP-XS Compression Nail System is inserted into the medullary canal of long bones for the :

- Alignment, stabilization, and fixation of fractures caused by disease or trauma
- The fixation of long bones that have been surgically prepared (osteotomy) for correction of deformity
- Arthrodesis

SLIM (Friedl) Gliding Nail Systems

Smith & Nephew SLIM (Friedl) Gliding Nail Systems Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew SLIM (Friedl) Gliding Nails and their cleared indications for use.

The SLIM (Friedl) Gliding Nail System is an all-purpose locking nail system for ensuring primary load stability in:

- Petrochanteric femoral fractures
- Subtrochanteric femoral fractures
- Lateral femoral neck fractures

Internal fixation with the SLIM (Friedl) Gliding Nail System is indicated in all combination injuries involving the lateral femoral neck or trochanter region and femoral shaft fractures. Thanks to its biomechanical characteristics, the SLIM (Friedl) Gliding Nail System is also suitable for medical femoral neck fractures with retention of the head and simple femoral shaft factures down to the distal metaphysis. Gliding nail fixation can also be used to secure pathological fractures or to provide weight-bearing stability after varus and valgus revision osteotomies of the proximal femur.

TriGen Low Profile Bone Screw

Smith & Nephew TriGen Low Profile Bone Screw Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew TriGen Low Profile Bone Screws and their cleared indications for use.

The TRIGEN™ Low Profile Bone Screw can be used with several types of nails in Smith & Nephew's (TRIGEN™) Titanium Nail System. The TRIGEN™ Low Profile Bone Screw therefore has the following indications:

Indications for interlocking intramedullary nails include simple long bone fractures; severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction following tumor resection and grafting; supracondylar fractures; bone lengthening and shortening. Interlocking intramedullary nails are indicated for fixation of

fractures that occur in and between the proximal and distal third of the long bones being treated.

In addition to the indications for interlocking intramedullary nails, devices that contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability (e.g. Femoral Antegrade Nail, Trochanteric Antegrade Nail and Femoral/Recon Antegrade Nail) are indicated for the following: subtrochanteric fractures, intertrochanteric fractures, and ipsilateral femoral shaft/neck fractures.

In addition to the indications for interlocking intramedullary nails, devices that use a retrograde femoral surgical approach (e.g. Knee Nail, Retrograde and Supracondylar Nails) are indicated for the following: comminuted supracondylar fractures with or without intra-articular extension; fractures that require opening the knee joint to stabilize the femoral condylar segment; fractures above total knee implants (peri-prosthetic fractures).

The TRIGEN™ InterTAN nails are indicated for fractures of the femur including: simple shaft fractures, comminuted shaft fractures, spiral shaft fractures, long oblique shaft fractures and segmental shaft fractures; subtrochanteric fractures; intertrochanteric fractures; ipsilateral femoral shaft/neck fractures; intracapsular fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction, following tumor resection and grafting; bone lengthening and shortening.

SURESHOT™ TAN Nails are indicated for fractures of the femur including simple long bone fractures, severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction, following tumor resection and grafting; supracondylar fractures; bone lengthening and shortening; and for fixation of fractures that occur in and between the *proximal third* and *distal fourth* of the femur.

In addition, SURESHOT™TAN Nails contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability and are indicated for the following: subtrochanteric fractures; intertrochanteric fractures; ipsilateral femoral shaft/neck fractures; and intracapsular fractures.

Substantial Equivalence Information

The device specific instruments associated with the implant devices with which they are used are considered substantially equivalent to previously cleared device specific instruments in that both subject and predicate instruments:

- Share the same raw materials;
- Are manufactured though the same processes;
- Utilize the same sterilization procedures; and
- Have similar nature of body contact

The Smith & Nephew IM Nail Systems Instruments are similar in design and function to competing IM nail instrumentation on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 19 2012

Smith & Nephew, Inc.
% Mr. Bradley Heil
7135 Goodlett Farms Parkway
Memphis, Tennessee 38016

Re: K122170
Trade/Device Name: Intramedullary Nail Systems Instruments
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: II
Product Code: HSB, HWC, JDS, KTT
Dated: July 19, 2012
Received: July 23, 2012

Dear Mr. Heil:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

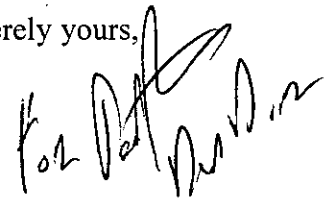
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Trigen Adolescent TAN Nail System and Trigen 130° TAN Nail System

Indications for Use:

Smith & Nephew Trigen Adolescent TAN Nail System and Trigen 130° TAN Nail System Instruments are accessory devices and are intended to be used to assist in the implantation of the Smith & Nephew Trigen Adolescent TAN Nail System and the Smith & Nephew Trigen 130° TAN Nail System and their cleared indications for use.

Indications for interlocking intramedullary nails include:

- Simple long bone fractures
- Severely comminuted, spiral, large oblique and segmental fractures
- Nonunions and malunions
- Poly trauma and multiple fractures
- Prophylactic nailing of impending pathologic fractures
- Reconstruction following tumor resection and grafting
- Supracondylar fractures
- Bone lengthening and shortening
- Fractures that occur in and between the proximal and distal third of the long bones being treated

In addition to the indications for interlocking intramedullary nails, devices that contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability are indicated for the following:

- Subtrochanteric fractures with lesser trochanteric involvement
- Ipsilateral femoral shaft/neck fractures
- Intertrochanteric fractures

Prescription Use __X__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122170

Indications for Use

510(k) Number (if known):

Device Name: Trigen Humeral Nail System

Indications for Use:

Smith & Nephew Trigen Nail System Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Trigen System and its cleared indications for use.

TRIGEN® Humeral Nail System is indicated for:

- Proximal and/or diaphyseal fractures of the humerus
- Nonunions
- Malalignments
- Pathological humeral fractures
- Impending pathological fractures

Prescription Use		AND/OR	Over-The-Counter Use	
(Part 21 CFR 801 Subpart D)	X		(21 CFR 807 Subpart C)	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122170

Indications for Use

510(k) Number (if known):

Device Name: Trigen InterTAN Nail System

Indications for Use:

Smith & Nephew Trigen InterTAN Nail System Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Trigen InterTAN Nail System and its cleared indications for use.

TRIGEN InterTAN Nails are indicated for:

- Simple long bone fractures
- Severely comminuted spiral, long oblique, and segmental shaft
- Nonunions and malunions
- Poly trauma and multiple fractures
- Prophylactic nailing of impending pathologic fractures
- Reconstruction, following tumor resection and grafting
- Bone lengthening and shortening
- Subtrochanteric fractures
- Ipsilateral femoral shaft/neck fractures
- Intertrochanteric fractures
- Intracapsular fractures

Prescription Use	X	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)			(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122170

Indications for Use

510(k) Number (if known):

Device Name: Intramedullary Nail Systems (Short Knee Nail, REVISION® Nail and Hindfoot Fusion Nail (HFN))

Indications for Use:

Smith & Nephew Intramedullary Nail Systems Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Intramedullary Nail Systems and their cleared indications for use.

The Short Knee Nail, REVISION® Nail and Hindfoot Fusion Nail (HFN) are indicated for:

- Degeneration, deformity, or trauma of both the tibiotalar and talocalcaneal articulations of the hindfoot
- Tibiocalcaneal arthrodesis
- Combined arthrodesis of the ankle and sub-talar joints
- Avascular necrosis of the ankle and sub-talar joints
- Failed total ankle replacement with sub-talar intrusion
- Failed ankle arthrodesis with insufficient talar body
- Rheumatoid arthritis
- Severe deformity secondary to untreated talipes equinovarus or neuromuscular disease
- Severe pilon fractures with trauma to the subtalar joint

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122170

Indications for Use

510(k) Number (if known):

Device Name: SURESHOT TAN Nail Systems

Indications for Use:

Smith & Nephew SURESHOT TAN Nail Systems Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew SURESHOT TAN Nail Systems and their cleared indications for use.

SURESHOT TAN Nails are indicated for:

- Fractures of the femur including:
  - simple long bone fractures
  - severely comminuted, spiral, large oblique and segmental fractures
- Non unions and malunions
- Poly trauma and multiple fractures
- Prophylactic nailing of impending pathologic fractures
- Reconstruction, following tumor resection and grafting
- Supracondylar fractures
- Bone lengthening and shortening
- Fixation of fractures that occur in and between the *proximal third* and *distal fourth* of the femur

In addition, SURESHOT TAN Nails contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability and are indicated for the following:

- Subtrochanteric fractures;
- Intertrochanteric fractures;
- Ipsilateral femoral shaft/neck fractures;
- Intracapsular fractures.

Prescription Use	X	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)			(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122170

Indications for Use

510(k) Number (if known):

Device Name: Intramedullary Hip Screw Systems

Indications for Use:

Smith & Nephew Intramedullary Hip Screw System Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Intramedullary Hip Screw Systems and their cleared indications for use.

Intramedullary Hip Screws are indicated for:

- Intracapsular fractures of the femoral neck;
- Trochanteric or subtrochanteric fractures;
- Osteotomies for patients with diseases or deformities of the hip;
- Hip arthrodesis;
- Supracondylar fractures and distal femoral fractures using a supracondylar plate;
- Ipsilateral femoral shaft/neck fractures;
- Intertrochanteric fractures;
- Femoral neck fractures;
- Subcapital fractures;
- Comminuted neck and shaft fractures;
- Femur reconstruction following tumor resection;
- Leg length discrepancies secondary to femoral inequality;
- Prophylactic nailing of impending pathologic fractures.

Prescription Use	X	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)			(21 CFR 807 Subpart C)

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510(k) Number K122170

Indications for Use

510(k) Number (if known):

Device Name: Ender Nail Systems

Indications for Use:

Smith & Nephew Ender Nail System Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Ender Nail Systems and their cleared indications for use.

ENDER Nails are indicated for:

- Fracture of the neck, trochanteric, and subtrochanteric region of the femur;
- Distal femoral fractures with a distal fragment 10cm or longer
- Tibial shaft fractures
- Proximal humeral fractures

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Surgical, Orthopedic,
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510(k) Number K122170

Indications for Use

510(k) Number (if known):

Device Name: TriMax Nail System

Indications for Use:

Smith & Nephew TriMax Nail System Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew TriMax Nail Systems and their cleared indications for use.

Femoral/Recon antegrade nails and retrograde nails are indicated for:

- Shaft fractures including severely comminuted, spiral, large oblique and segmental fractures
- Non-unions and malunions
- Bone lengthening/shortening
- Severely comminuted shaft fractures
- Pathologic fractures, pseudoarthrosis, failed osteosynthesis
- Closed supracondylar fractures
- Prophylactic nailing of impeding pathologic fractures

Additonal indications for the femoral/recon antegrade include:

- Subtrochanteric fractures with lesser trochanteric involvement
- Ipsilateral femoral shaft/neck fractures

Additonal indications for retrograde nails include:

- Severly comminuted supracondylar fractures with or without difficult intra-articular extension
- Fractures that require opening the knee joint to stabilize the femoral condylar segmarnt
- Fractures above total knee implants

The TriMax Nail System is intended to be removed upon fracture healing.

Prescription Use	X	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)			(21 CFR 807 Subpart C)

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and Restorative Devices

510(k) Number K122170

Indications for Use

510(k) Number (if known):

Device Name: TriGen Meta-Nail Retrograde Femoral & Tibial Nails

Indications for Use:

Indications for interlocking intramedullary nails include:

- Simple long bone fractures
- Severely comminuted, spiral, large oblique and segmental fractures
- Nonunions and malunions
- Poly trauma and multiple fractures
- Prophylactic nailing of impending pathologic fractures
- Reconstruction following tumor resection and grafting
- Supracondylar fractures
- Bone lengthening and shortening
- Fractures that occur in and between the proximal and distal third of the long bones being treated

In addition to the indications for interlocking intramedullary nails, devices that contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability (e.g. Femoral Antegrade Nail, Trochanteric Antegrade Nail and Femoral/Recon Antegrade Nail) are indicated for the following:

- Subtrochanteric fractures
- Intertrochanteric fractures
- Ipsilateral femoral shaft/neck fractures

In addition to the indications for interlocking intramedullary nails, devices that use a retrograde femoral surgical approach (e.g. Knee Nail, Retrograde and Supracondylar Nails) are indicated for:

- Comminuted supracondylar fractures with or without intra-articular extension
- Fractures that require opening the knee joint to stabilize the femoral condylar segment
- Fractures above total knee implants (peri-prosthetic fractures)

Prescription Use	X	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)			(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122170

Indications for Use

510(k) Number (if known):

Device Name: IP-XS Compression Nail System

Indications for Use:

Smith & Nephew IP-XS Compression Nail System Instruments are accessory devices and are intended to be used to assist in the implantation of the Smith & Nephew IP-XS Compression Nail System and its cleared indications for use.

The IP-XS Compression Nail System is inserted into the medullary canal of long bones for the :

- Alignment, stabilization, and fixation of fractures caused by disease or trauma
- The fixation of long bones that have been surgically prepared (osteotomy) for correction of deformity
- Arthrodesis

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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510(k) Number K122170

Indications for Use

510(k) Number (if known):

Device Name: SLIM (Friedl) Gliding Nail Systems

Indications for Use:

Smith & Nephew SLIM (Friedl) Gliding Nail Systems Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew SLIM (Friedl) Gliding Nails and their cleared indications for use.

The SLIM (Friedl) Gliding Nail System is an all-purpose locking nail system for ensuring primary load stability in:

- Petrochanteric femoral fractures
- Subtrochanteric femoral fractures
- Lateral femoral neck fractures

Internal fixation with the SLIM (Friedl) Gliding Nail System is indicated in all combination injuries involving the lateral femoral neck or trochanter region and femoral shaft fractures. Thanks to its biomechanical characteristics, the SLIM (Friedl) Gliding Nail System is also suitable for medical femoral neck fractures with retention of the head and simple femoral shaft factures down to the distal metaphysis. Gliding nail fixation can also be used to secure pathological fractures or to provide weight-bearing stability after varus and valgus revision osteotomies of the proximal femur.

Prescription Use	X	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)			(21 CFR 807 Subpart C)

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510(k) Number K122170

Indications for Use

510(k) Number (if known):

Device Name: TriGen Low Profile Bone Screw

Indications for Use:

Smith & Nephew TriGen Low Profile Bone Screw Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew TriGen Low Profile Bone Screws and their cleared indications for use.

The TRIGEN™ Low Profile Bone Screw can be used with several types of nails in Smith & Nephew's (TRIGEN™) Titanium Nail System. The TRIGEN™ Low Profile Bone Screw therefore has the following indications:

Indications for interlocking intramedullary nails include simple long bone fractures; severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction following tumor resection and grafting; supracondylar fractures; bone lengthening and shortening. Interlocking intramedullary nails are indicated for fixation of fractures that occur in and between the proximal and distal third of the long bones being treated.

In addition to the indications for interlocking intramedullary nails, devices that contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability (e.g. Femoral Antegrade Nail, Trochanteric Antegrade Nail and Femoral/Recon Antegrade Nail) are indicated for the following: subtrochanteric fractures, intertrochanteric fractures, and ipsilateral femoral shaft/neck fractures.

In addition to the indications for interlocking intramedullary nails, devices that use a retrograde femoral surgical approach (e.g. Knee Nail, Retrograde and Supracondylar Nails) are indicated for the following: comminuted supracondylar fractures with or without intra-articular extension; fractures that require opening the knee joint to stabilize the femoral condylar segment; fractures above total knee implants (peri-prosthetic fractures).

The TRIGEN™ InterTAN nails are indicated for fractures of the femur including: simple shaft fractures, comminuted shaft fractures, spiral shaft fractures, long oblique shaft fractures and segmental shaft fractures; subtrochanteric fractures; intertrochanteric fractures; ipsilateral femoral shaft/neck fractures; intracapsular fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction, following tumor resection and grafting; bone lengthening and shortening.

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SURESHOT™ TAN Nails are indicated for fractures of the femur including simple long bone fractures, severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction, following tumor resection and grafting; supracondylar fractures; bone lengthening and shortening; and for fixation of fractures that occur in and between the *proximal third* and *distal fourth* of the femur.

In addition, SURESHOT™TAN Nails contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability and are indicated for the following: subtrochanteric fractures; intertrochanteric fractures; ipsilateral femoral shaft/neck fractures; and intracapsular fractures.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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510(k) Number K122170